



1633  
BOX PATENT  
Attorney Docket No. 23057-XY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **RECEIVED**

In re Application of

JUL 08 2002

PATIERNO et al.

Serial No. 10/052,498

Group Art Unit: 1633

TECH CENTER 1600/1000

Filed: January 23, 2002

Examiner: Not assigned

For: **UTEROGLOBIN GENE THERAPY FOR EPITHELIAL CELL CANCER**

**TRANSMITTAL LETTER**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1) Transmittal Letter;
- (2) Information Disclosure Statement; and
- (3) Form PTO-1449.

The Commissioner is hereby specifically authorized to charge any required fee, or credit any overpayment, in connection with this matter to deposit Account No. 14-0112.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

Date: July 3, 2002

By: 

Todd L. Juneau  
Reg. No. 40,669  
Lee C. Heiman  
Registration No. 41,827  
Customer No. 20529

**NATH & ASSOCIATES PLLC**  
1030 15<sup>th</sup> Street N.W., 6<sup>th</sup> Floor  
Washington, D.C. 20005-1503  
Tel: (202) 775-8383  
Fax: (202) 775-8396  
GMN:TLJ:LCH IDS.tl.wpd



PATENT  
Attorney Docket No. 23057-XY

*Handwritten initials and date:*  
7/1/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **RECEIVED**

In re Application of

JUL 03 2002

PATIERNO et al.

10/052,498

Serial No. 10/052,498

Group Art Unit: 1633

Filed: January 23, 2002

Examiner: Not assigned

For: **UTEROGLOBIN GENE THERAPY FOR EPITHELIAL CELL CANCER**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to Applicants' duty of disclosure under 37 C.F.R. §§ 1.56 and 1.97-1.99, the documents listed on the attached Form PTO-1449 are being brought to the attention of the Examiner in charge of the captioned application. No fee is required for this submission because it is submitted within three months from the filing date or before a First Action on the Merits has been mailed by the U.S. Patent and Trademark Office.

Copies of the documents are not required to be provided because they were previously submitted to, or cited by, the Patent Office in prior U.S. Patent Application No. 08/987,502, filed December 9, 1997, U.S. Patent Application No. 09/556,467, filed April 21, 2000, U.S. Patent Application No. 08/966,196, filed November 7, 1997, U.S. Patent Application Serial Number 08/658,796, filed June 5, 1996, U.S. Patent Application Serial Number

Attorney Docket No.: 23057-XY  
Serial No.: 10/052,498

08/486,203, filed June 7, 1995, and U.S. Patent Application Serial Number 08/400,084, filed March 7, 1995. The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

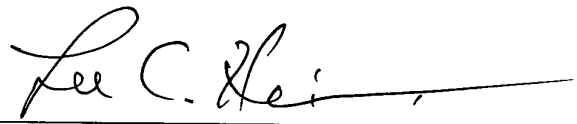
The Examiner is welcomed to telephone the undersigned attorney if (s)he has any questions or comments.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

Date: July 3, 2002

By:



Todd L. Juneau  
Reg. No. 40,669  
Lee C. Heiman  
Registration No. 41,827  
Customer No. 20529

**NATH & ASSOCIATES PLLC**  
1030 15<sup>th</sup> Street, NW - 6<sup>th</sup> Floor  
Washington, D.C. 20005  
Tel: (202) 775-8383  
Fax: (202) 775-8396  
GMN/LCH IDS.wpd



FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498

Applicant

PATIERNO et al.

Filing Date

January 23, 2002

Group Art Unit

1633

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Sub-Class	Filing Date
	AA	5,662,896	09/02/97	Barber et al.	424	93	03/17/93
	AB	5,373,095	12/13/94	Johnson et al.	540	95	09/23/93
	AC	5,359,078	10/25/94	Kohn et al.			12/04/92
	AD	5,284,827	02/08/94	Maione et al.	514	12	10/19/90
	AE	5,266,562	11/30/93	Mukherjee et al.	514	15	11/19/87
	AF	5,086,164	02/04/92	Maione et al.	530	324	12/27/89
	AG	4,920,016	04/24/90	Allen et al.	424	450	12/18/87
	AH						

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Sub-Class	Translation
	AI	WO 91/07187	5/1991	WO			Yes
	AJ						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AK		Hill, Richard P., Chapter 11, <i>Metastasis</i> , pp. 178-95 in <i>The Basic Science of Oncology</i> , Tannock et al., Eds., McGraw-Hill, N.Y. (1992).
	AL		Aznavorian, Sadie et al., "Molecular Aspects of Tumor Cell Invasion and Metastasis," <i>Cancer</i> , 1993, 71(4), 1368-1383.
	AM		Singh, Gurmukh et al., "Amino-acid and cDNA nucleotide sequences of human Clara cell 10 kDa protein," <i>BBA</i> , 1988, 950, 329-337.
	AN		Nieto, A. et al., "Purification and Quaternary Structure of the Hormonally Induced Protein Uteroglobin," <i>Arch. Biochem. Biophys.</i> , 1977, 180, 82-92.
	AO		Mantile, Giuditta et al., "Human Clara Cell 10-kDa Protein Is the Counterpart of Rabbit Uteroglobin," <i>J. Biol. Chem.</i> , 1993, 268(27), 20343-20351.

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to Applicant.



FORM PTO-1449

**INFORMATION DISCLOSURE CITATION**Attorney Docket  
23057-XYSerial Number  
10/052,498Applicant  
PATIERNO et al.Filing Date  
January 23, 2002Group Art Unit  
1633**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Sub-Class	Filing Date
						JUL 08 2002

**FOREIGN PATENT DOCUMENTS**

Document Number	Date	Country	Class	Sub-Class	Translation
					Yes No

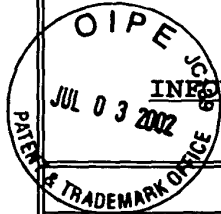
**OTHER** (Including Author, Title, Date, Pertinent Pages, etc.)

BA	Miele, Lucio et al., "Uteroglobin: Structure, Molecular Biology, and New Perspectives on Its Function as a Phospholipase A <sub>2</sub> Inhibitor," <u>Endocrine Reviews</u> , 1987, 8(4), 474-90.
BB	Miele, Lucio et al., "High Level Bacterial Expression of Uteroglobin, a Dimeric Eukaryotic Protein with Two Interchain Disulfide Bridges, in Its Natural Quaternary Structure," <u>J. Biol. Chem.</u> , 1990, 265(11), 6427-35.
BC	Sambrook, J. et al., <u>Molecular Cloning: A Laboratory Manual</u> , 2nd Ed., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y. (1989).
BD	Arcone, Rosaria et al., "Structural characterization of a biologically active human lipocortin 1 expressed in <i>Escherichia coli</i> ," <u>Eur. J. Biochem.</u> , 1993, 211, 347-55.
BE	Cirino, G. et al., "Anti-inflammatory actions of an N-terminal peptide from human lipocortin 1," <u>British J. Pharmacol.</u> , 1993, 108, 573-574.
BF	Bastian, Boris Christoph et al., "Inhibition of Human Skin Phospholipase A <sub>2</sub> by "Lipocortins" Is an Indirect Effect of Substrate/Lipocortin Interaction," <u>J. Invest. Dermatol.</u> , 1993, 101(3), 359-63.
BG	Ritter, Mary A. et al., Eds., <u>Monoclonal Antibodies - Production, Engineering and Clinical Applications</u> , Cambridge University Press, Cambridge, UK (1995).
BH	Budavari, Susan et al., Eds., <u>The Merck Index</u> , 11th Ed., Merck & Co., Inc., Rahway, N.J. (1989).
BI	Gilman, Alfred Goodman et al., Eds., <u>Goodman and Gilman's: The Pharmacological Bases of Therapeutics</u> , 8th Ed., Pergamon Press, U.S.A. (1990).

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to Applicant.



FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498Applicant  
PATIERNO et al.Filing Date  
January 23, 2002Group Art Unit  
1633

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-Class	Filing Date
						JUL 08 2002

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Sub-Class	Trans-lation
					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

CA	Remington's Pharmaceutical Sciences, 17th Ed., Mack Publishing Co., Easton, PA (1990).
CB	Goldenberg, David M., Ed., <u>Cancer Therapy With Radiolabeled Antibodies</u> , CRC Press, Boca Raton, FL (1995).
CC	Stone, Kenneth R. et al., "Isolation of a Human Prostate Carcinoma Cell Line (DU 145)," <u>Int. J. Cancer</u> , 1978, 21, 274-281.
CD	Horoszewicz, Julius S. et al., "LNCaP Model of Human Prostatic Carcinoma," <u>Cancer Res.</u> , 1983, 43, 1809-18.
CE	Kaighn, M.E. et al., "Establishment and Characterization of a Human Prostatic Carcinoma Cell Line (PC-3)," <u>Invest. Urol.</u> , 1979, 17(1), 16-23.
CF	Hzumi, Tatsuo et al., "Establishment of a New Prostatic Carcinoma Cell Line (TSU-PR1)," <u>J. Urology</u> , 1987, 137, 1304-1306.
CG	Albini, A. et al., "A Rapid in Vitro Assay for Quantitating the Invasive Potential of Tumor Cells," <u>Cancer Research</u> , 1987, 47, 3239-3245.
CH	Leyton, J. et al., "Recombinant Human Uteroglobulin Inhibits the in Vitro Invasiveness of Human Metastatic Prostate Tumor Cells and the Release of Arachidonic Acid Stimulated by Fibroblast-conditioned Medium," <u>Cancer Research</u> , 1994, 54, 3696-3699.
CI	Frandsen, T.L. et al., "Assays for the Study of Human Cancer Cell Invasion and Metastasis," <u>Fibrinolysis</u> , 1992, 6 (Supp. 4), 71-76.

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498

Applicant

PATIERNO et al.

Filing Date

January 23, 2002

Group Art Unit

1633

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub- Class	Filing Date

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Sub- Class	Trans- lation
					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

DA		Manyak, Michael J. et al., "Expression of a Uteroglobin-Like Protein in Human Prostate," <u>J. Urology</u> , 1988, 140, 176-182.
DB		Leyton, J. et al., "Recombinant Human Uteroglobin Inhibits the <i>in Vitro</i> Invasiveness of Human Metastatic Prostate Tumor Cells and the Release of Arachidonic Acid Stimulated by Fibroblast-conditioned Medium," <u>Cancer Research</u> , 1994, 54, 1-4.
DC		Jensen, Sandra M. et al., "Clara Cell 10 kDa Protein mRNA in Normal and Atypical Regions of Human Respiratory Epithelium," <u>Int. J. Cancer</u> , 1994, 58, 629-637.
DD		Linnoila, R. Ilona et al., "Peripheral Airway Cell Marker Expression in Non-Small Cell Lung Carcinoma," <u>A.J.C.P.</u> , 1992, 97(2), 233-243.
DE		Broers, Jos L. V. et al., "Expression of Surfactant Associated Protein-A and Clara Cell 10 Kilodalton mRNA in Neoplastic and non-Neoplastic Human Lung Tissue as Detected by <i>In situ</i> Hybridization," <u>Lab. Invest.</u> , 1992, 66(3), 337-346.
DF		Peri, Alessandro et al., "Tissue-specific Expression of the Gene Coding for Human Clara Cell 10-kD Protein, a Phospholipase A <sub>2</sub> -inhibitory Protein," <u>J. Clin. Invest.</u> , 1993, 92, 2099-2109.
DG		Miyamoto et al., <u>J. Urology</u> , 149: 1015-1019 (May 1993).
DH		Morgan et al., <u>Annu. Rev. Biochem.</u> , 62: 191-217 (1993).

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498Applicant  
PATIERNO et al.Filing Date  
January 23, 2002Group Art Unit  
1633

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub- Class	Filing Date

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Sub- Class	Trans- lation
					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

EA		Tolstoshev, <i>Annu. Rev. Pharmacol. Toxicol.</i> , 32: 573-96 (1993).
EB		Leyton et al., <i>Proc. Amer. Assoc. Canc. Res.</i> 35: 280 (1994).
EC		Mayer et al., <i>Expert Opin. Invest. Drugs</i> , 5: 535-554 (1996).
ED		Osband et al., <i>Immunology Today</i> , 11: 193-195 (1990).
EE		Dannhorn et al., <i>J. Immunol. Meth.</i> , 119: 223-230 (1989).
EF		Tibes et al., <i>Expert Opin. Invest. Drugs</i> , 6: 279-298 (1997).
EG		Aumuller et al., <i>Histochemistry</i> , 83: 413-417 (1985).
EH		López de Haro et al., <i>FEBS LETTERS</i> , 232: 351-353 (1988).
EI		Cerbón et al., <i>J. Steroid Biochem.</i> , 36: 1-6 (1990).
EJ		Aihara, T. et al., <i>Can. Lett.</i> 150(79-84), 2000.
EK		Anderson et al., Human gene therapy, 1998, <i>Nature</i> , vol. 392, pp. 25-30.

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to Applicant.



FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498Applicant  
PATIERNO et al.Filing Date  
January 23, 2002Group Art Unit  
1633

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub- Class	Filing Date

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Sub- Class	Trans- lation
					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

FA	Bodey et al., Failure of cancer vaccines: The significant limitations of this approach to immunotherapy, 2000, Anticancer Research, vol. 20, pp. 2665-2676.
FB	Bowie et al., Science 247:1306-1310, 1990.
FC	Chiu et al., optimizing energy potenetials for success in protein tertiary structure prediction, 1998, Folding & Design, vol. 3, pp. 223-228.
FD	Gomez-Navarro et al., Gene therapy for cancer, 1999, European Journal of Cancer, vol. 35, pp. 867-885.
FE	Liotta, LA Scientific American, pp 54-63, Feb. 1992.
FF	Manyak et al., Uteroglobin inhibition of prostate adenocarcinoma invasion in vitro: A new class of tumor suppressor genes, 1995, The Journal Urology, 153:969.
FG	Ngo et al., The Protein Folding Problem and Tertiary Structure, pp. 492-496, 1994.
FH	Sethna et al., Lung-tumor directed gene therapy using neuroendocrine and lung-tissue specific promoters, 1997, vol. 38, pp. 379.
FI	Shuman et al., Histological presence of viable prostatic glands on routine biopsy following cryosurgical ablation of the prostate, 1997, The Journal of Urology, vol. 157, pp. 552-555.
FJ	Verma et al., Gene therapy-promises, problems and prospects, 1997, Nature, vol. 389, pp. 239-242.

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE CITATION

Attorney Docket  
23057-XYSerial Number  
10/052,498

Applicant

PATIERNO et al.

Filing Date

January 23, 2002

Group Art Unit

1633

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-Class	Filing Date

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Sub-Class	Translation
					Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

GA		Vile et al., Cancer gene therapy: hard lessons and new courses, 2000, Gene Therapy, vol. 7, pp. 2-8.
GB		Watson, MA et al., Can. Res. 59(3028-3031), Jul. 1999.
GC		Wells, Biochemistry 29:8509-8517, 1990.
GD		
GE		
GF		
GG		
GH		
GI		

RECEIVED

JUL 6 6 2002

TECH CENTER 10

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to Applicant.